

AUG 8 - 2005

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K05499.

<b>1. Submitted by:</b>	Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL 60060 Phone: (847) 996-4675 FAX: (847) 996-4655 Contact person: Nina Gamperling Date prepared: May 5, 2005
<b>2. Name of Device:</b>	<u>Trade or proprietary name:</u> IPF (Immature Platelet Fraction) parameter on the Sysmex® XE-2100, Automated Hematology Analyzer.  <u>Common name:</u> IPF parameter  <u>Classification name:</u> IPF parameter Automated Differential Cell Counter, Sysmex® XE-2100 (21 CFR 864.5220)
<b>3. Predicate Device:</b>	The IPF parameter on the Sysmex® XE-2100 is substantially equivalent to the reticulated platelet on the FACSCalibur flow cytometric method.
<b>4. Device Description:</b>	The Sysmex XE-2100 uses a gating system in the optical (fluorescence) reticulocyte/platelet channel to quantify the immature platelets. (Note: XE IPF master with XE pro is required to obtain results described.)
<b>5. Intended Use:</b>	The IPF% (Immature Platelet Fraction) on the Sysmex® XE-2100 for <i>in Vitro</i> diagnostics is used to enumerate the immature platelet fraction.
<b>6. Substantial equivalence-similarities and differences</b>	The following table compares the IPF parameter with predicate method.

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

**Comparison Table to Predicate Method**

	<b>FACSCalibur</b>	<b>IPF% parameter on XE-Series</b>
	<b>Predicate</b>	<b>New method</b>
<b>Intended Use</b>	Using surrogate markers and gating strategies to identify reticulated platelets.	For <i>in Vitro</i> diagnostics use to enumerate the immature platelet fraction.
<b>Methodology</b>	Enumeration of reticulated platelets (immature platelets) by flow cytometry	Enumeration of the IPF% (immature platelet fraction) by the XE-2100, automated hematology analyzer
<b>Type of Anticoagulant</b>	EDTA	EDTA
<b>Specimen Type</b>	Peripheral blood	Peripheral blood

### 7. Clinical Performance Data:

Studies were performed to evaluate the equivalency of the IPF parameter to the predicate method. Results indicate equivalent performance.

### 8. Conclusions:

The performance data demonstrated substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Nina M. Gamperling, MBA, MT (ASCP), RAC  
Manager, Regulatory Affairs  
Sysmex America, Inc.  
One Nelson C. White Parkway  
Mundelein, Illinois 60060

AUG 8 - 2005

Re: k051199  
Trade/Device Name: Immature Platelet Fraction (IPF) on Sysmex® XE-2100,  
Automated Hematology Analyzer  
Regulation Number: 21 CFR § 864.5220  
Regulation Name: Automated differential cell counter  
Regulatory Class: II  
Product Code: GKZ  
Dated: May 5, 2005  
Received: May 10, 2005

Dear Ms. Gamperling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

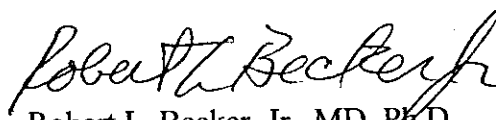
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert L. Becker, Jr.", is positioned above the typed name.

Robert L. Becker, Jr., MD, Ph.D

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K051199

Device Name: IPF (Immature Platelet Fraction) parameter on the Sysmex®  
XE-2100™, Automated Hematology Analyzers

### Indications For Use:

The IPF% (Immature Platelet Fraction) on the Sysmex® XE-2100 for *in Vitro* diagnostics is used to enumerate the immature platelet fraction.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CHRD, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use ☐

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety